STATUTORY INSTRUMENTS.

S.I. No. 238 of 2023

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (No. 3) REGULATIONS 2023

S.I. No. 238 of 2023

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (No. 3) REGULATIONS 2023

I, STEPHEN DONNELLY, Minister for Health, in exercise of the powers conferred on me by section 32 (as amended by section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006)) of the Irish Medicines Board Act 1995 (No. 29 of 1995), hereby make the following regulations:

1. (1) These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2023.

(2) The collective citation "the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2023" includes these Regulations.

2. In these Regulations "Principal Regulations" means the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003).

3. The Principal Regulations are amended –

(a) in Regulation 4(1) (as amended by Regulation 3 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2021 (S.I. No. 81 of 2021)) by substituting for the definition of "clinical practice guidelines" the following:

"'clinical practice guidelines' or "CPG" means the clinical practice guidelines prepared and published by the Pre-Hospital Emergency Care Council or in the case of Naloxone only means the clinical practice guidelines prepared and published by the Pre-Hospital Emergency Care Council or the Health Service Executive;",

(b) in Regulation 4C (inserted by Regulation 4 of the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015 (S.I. No. 449 of 2015)) by substituting for paragraph (c) the following paragraph:

"(c) the person supplying and administering the medicinal product has been issued with a certificate stating that he or she has satisfactorily completed a course of training, approved by the Pre-Hospital Emergency Care Council or, in the case of Naloxone only, approved by the Pre-Hospital Emergency Care Council or the Health Service Executive, in the use of the specific medicinal product, relating to the administration of the medicinal product, the

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 19*th May,* 2023.

management of any immediate adverse reaction that may follow from such administration, the storage and safe keeping of the medicinal product and the clinical practice guidelines and record-keeping requirements for administration of the medicinal product,",

and

(c) in the Tenth Schedule (as amended by Regulation 6 of the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2018 (S.I. No. 530 of 2018)) –

(i) by substituting for the text in column 3 of the entry for "Naloxone hydrochloride dihydrate 1mg/ml pre-filled injection" the following:

"Adults and children: For the emergency treatment of respiratory depression secondary to known or suspected narcotic overdose in accordance with Clinical Practice Guidelines approved by the Pre-Hospital Emergency Care Council or the Health Service Executive.", and

(ii) by substituting for the text in column 3 of the entry for "Naloxone hydrochloride Nasal administration dihydrate 1.8mg nasal spray" the following:

"Adults and children: For the emergency treatment of respiratory depression secondary to known or suspected narcotic overdose in accordance with Clinical Practice Guidelines approved by the Pre-Hospital Emergency Care Council or the Health Service Executive.".

L.S.

GIVEN under my Official Seal,
16 May, 2023.

STEPHEN DONNELLY,
Minister for Health.

EXPLANATORY NOTE

(*This note is not part of the Instrument and does not purport to be a legal interpretation.*)

These Regulations amend the Medicinal Products (Prescription and Control of Supply) Regulations 2003.

The purpose of these Regulations is to provide for the approval of courses by the Health Service Executive for persons who may supply and administer Naloxone in an emergency.

These Regulations also provide for the Health Service Executive to prepare and publish clinical practice guidelines for the supply and administration of Naloxone.

These Regulations may be cited as the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2023.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
BÓTHAR BHAILE UÍ BHEOLÁIN,
CILL MHAIGHNEANN,
BAILE ÁTHA CLIATH 8,
D08 XAO6

Teil: 046 942 3100
r-phost: publications@opw.ie

DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
MOUNTSHANNON ROAD,
KILMAINHAM, DUBLIN 8,
D08 XAO6

Tel: 046 942 3100
E-mail: publications@opw.ie

ISBN 978-1-3993-2388-8

€ 3.00

(DH-478) 75. 5/23. Propylon.